IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF SUZANNE PARISIAN, M.D., RELATING TO THE TVT-SECUR DEVICE [WAVE 2]

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") move to exclude the testimony of Plaintiffs' expert, Suzanne Parisian, M.D., as to the TVT-Secur device for the three cases identified in Exhibit A.

This motion differs from that filed by Ethicon in Wave I. (ECF Nos. 2079 & 2080). In Wave I, Plaintiffs designated Dr. Parisian in cases involving two different products for which Dr. Parisian produced expert reports: Prolift + M and TVT-Secur. In Wave II, however, Plaintiffs did not designate Dr. Parisian as an expert for any Prolift + M case. Instead, Dr. Parisian has been designated in three cases involving only the TVT-Secur device. Accordingly, the instant motion seeks to exclude Dr. Parisian's opinions as to the TVT-Secur only.

INTRODUCTION

Dr. Suzanne Parisian is a non-practicing pathologist. She dons the title of "regulatory expert," but as a well-traveled advocate for the plaintiffs' bar, she has testified on seemingly limitless numbers of pharmaceutical products—and every imaginable subject pertaining to those products. Dr. Parisian is accordingly the subject of countless decisions from federal courts across the country. Some courts have permitted her to testify, often on limited topics. Yet

oftentimes courts have described her opinions as "astonishing," "egregious,"[1] and "woefully deficient,"[2] and have excluded her testimony. In the *Prempro* MDL, the United States Court of Appeals for the Eighth Circuit affirmed the District Court's post-trial decision to strike Dr. Parisian's entire trial testimony because she refused to abide by the court's rulings that limited her testimony. *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009). In a lengthy opinion devoted to her tactics, the *Prempro* MDL court cautioned: "Dr. Parisian's punitive damages stage testimony reveals 'how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis.'" *In re Prempro*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008).

Here, Dr. Parisian has prepared a report on the TVT-Secur, which contains 13 opinions that frequently overlap one another—and are in some instances subject to exclusion on more than one ground. *See* Exh. B: Suzanne Parisian Expert Witness Report, Jan. 30, 2016: TVT-Secur

---

[1] *In re Trasylol Prods. Liab. Litig.*, 709 F.Supp.2d 1323, 1342-1343 (S.D. Fla. 2010) (S.D. Fla. 2010) ("An instance I found particularly egregious was Dr. Parisian's apparent effort to construct a factual scenario, entirely divorced from any regulatory expertise, to support the Plaintiffs' theory as to Bayer's knowledge…Dr. Parisian's willingness to offer 'expert' opinion on such flimsy evidence and withhold any disclosures in advance is simply astonishing."). That court also stated:

> Plainly stated, Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding the opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon inference in order to offer her "takeaway" or "take home message" with respect to intent, knowledge, or causation in a manner unrelated to any regulatory expertise. Her testimony is unreliable and would not be of assistance to the jury.

Id. at 1351.

[2] *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp.2d 644, 666 (D. N.J. 2008) (scientific conclusions were "woefully deficient" and "nothing more than pure speculation").

("TVT-S Rep.").[3] Given the nature of this report—properly dubbed here as a "labyrinth" as other Courts have found—it is most logical to categorize her various opinions. Her testimony should be excluded for the following reasons:

First, although Dr. Parisian claims to be a "regulatory expert," her reports and deposition testimony reveal that she will try to offer opinions on highly scientific topics running the gamut from product development, standard of care, and medical causation. She is not qualified to do so and does not employ a reliable methodology for the panoply of opinions she intends to offer.

Second, Dr. Parisian states that she will not testify on corporate state of mind or intent, but her reports and testimony are full of personal beliefs that Ethicon is a bad actor. This should be excluded because Dr. Parisian is not qualified and does not have a reliable methodology. This testimony is also irrelevant and not helpful to the trier of fact.

Third, Dr. Parisian's regulatory opinions are inadmissible to the extent she frequently cites to Ethicon allegedly misleading the FDA, or withholding information from the FDA—topics which this Court has ruled are not relevant. Her regulatory opinions also amount to impermissible "narrative" testimony and constitute legal conclusions.

Fourth, Dr. Parisian should not be permitted to opine on foreign regulatory matters because she is not qualified, does not employ a reliable methodology, and the testimony would not be helpful to the jury.

Fifth, Dr. Parisian's testimony about the TVT-Secur's warnings should be excluded because she is not qualified and fails to employ a reliable methodology.

---

[3] In Wave II, Plaintiffs adopted Dr. Parisian's Wave I report. *See* Pl. Design. of Expert Witnesses.

Sixth, Dr. Parisian should not be permitted to testify as to any product other than the TVT-Secur, the only product for which she was designated and supplied an expert report.

ARGUMENT

I. Legal Standard

Ethicon incorporates the standard for the instant motion as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014).

II. Law & Analysis

A. Dr. Parisian is not qualified to offer any scientific opinions on causation, product development, risks, design, testing, manufacturing, studies, or the standard of care for treating physicians.

(1) Although Dr. Parisian claims her focus is regulatory, her report and testimony are replete with opinions on highly scientific issues.

As a threshold issue, it is important to note—and debunk—the topics upon which Dr. Parisian seeks to opine. Several courts have similarly noted—and addressed—opinions that Dr. Parisian claims she will not offer, but ultimately tries to. *See, e.g.*, *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 467 (E.D. N.Y. 2011) ("The Court finds that the Plaintiffs' assertion that Dr. Parisian does not offer such opinions to be disingenuous.").[4]

Here, Dr. Parisian's report states that she will not "address medical causation or standard of care in terms of the treating physicians," TVT-S Rep. ¶14, 23, and she testified at deposition that she would not offer any general or specific causation opinions. Exh. C: Parisian 3/8/16

[4] Comments by a state court judge in a mesh trial confirm this concern. There, the judge acknowledged "some indication from counsel that this witness tends to go far afield. And we need to make sure and corral this witness that instead of expressing generalized opinions be based again on her expertise with FDA approval processes and federal regulations." *See* Pl. Resp. to Wave I Motion to Exclude Dr. Parisian (ECF. No. 2148) at Exhibit 1, at 21:7-12; *see also* Ethicon Reply in Support of Mot. to Exclude Dr. Parisian (ECF. No. 2229).

Prolift +M Dep. Tr. ("PM Dep.") 46:11-47:6.[5] She also testified that she would not offer any opinion about manufacturing defect issues. *See id.* 48:3-49:6. Despite these statements, Dr. Parisian's report—and her testimony—reveal that she seeks to delve far into the realm of science. Illustrative examples include the following:

TVT-S REPORT
OPINION #1 - ETHICON's 510(K) FAILED TO ADEQUATELY DESCRIBE A FULL AND ACCURATE DISCLOSURE OF THE MANY SIGNIFICANT DIFFERENCES BETWEEN TVT-SECUR (A NEW SIS MINI TAPE) AND THE TVT AND TVT-O SYSTEM PREDICATES ORIGINALLY CITED BY ETHICON. ETHICON FAILED TO DESCRIBE RISKS ASSOCIATED WITH THE DEVICE PRIOR TO CLEARANCE. DESPITE THE FORESEEABLE AND UNANSWERED RISKS REMAINING FOR IMPLANTING WOMEN WITH A NEW MINI SLING, ETHICON WAS ABLE TO REFERENCE GYNE IDEAS' MINI TAPE DEVICE AS A PREDICATE AND AVOID OBTAINING CLINICAL DATA PRIOR TO 510(K) CLEARANCE. OPINION #2 - ETHICON KNEW THERE WERE NEW RISKS FOR SIS MINI SLING WHEN COMPARED TO TVT AND TVT-O SYSTEMS BASED ON CHANGES MADE TO HELP REDUCE COSTS. HOWEVER, ETHICON CHOSE NOT TO STUDY THE IMPACT OF THOSE CHANGES FOR PATIENT SAFETY. ETHICON DID NOT UPDATE ITS TVT-SECUR IFU TO ADEQUATELY WARN OF INCREASED RISKS FOR PREMATURE FAILURE, CHRONIC PAIN, DYSPAREUNIA, MESH EXTRUSION AND EROSION, CHRONICITY AND WORSENING OF SYMPTOMS, DIFFICULTIES WITH MESH REMOVAL, DIFFICULTIES WITH INSERTER FUNCTION AND PATIENT NEED FOR ADDITIONAL SURGERY. OPINION #3 - ETHICON, DESPITE HAVING MADE SPECIFIC ASSURANCES TO ITS OWN MEDICAL INVESTIGATORS THAT CERTAIN ADDITIONAL SAFETY STUDIES WOULD BE PERFORMED DID NOT LIVE UP TO THAT AGREEMENT. OPINION #4 - ETHICON'S MARKETING FOR TVT-S TARGETED SURGEONS WITHOUT REGARD AS TO PELVIC SURGERY EXPERIENCE, MINIMIZING DIFFICULTIES FOR PLACEMENT OF THE MINI SLING, INACCURATELY CALLING IT 'LESS INVASIVE'

[5] Although Dr. Parisian was not designated on Prolift + M cases in Wave II, her deposition testimony from that product (taken the same day, March 8, 2016) is incorporated to the extent it is relevant to the arguments herein, as is Ethicon's briefing from its initial Motion to Exclude (Doc. Nos. 2079 (Mot. to Exclude), 2080 (Mem. in Support)). For instance, the transcript from Dr. Parisian's TVT-Secur deposition reflects that many issues—such as Dr. Parisian's background, training and experience—were discussed during the earlier Prolift + M deposition and not duplicated during the TVT-Secur deposition.

WHILE KNOWING THE PROCEDURE HAD A SIGNIFICANT SURGEON LEARNING CURVE, THE ‘U’ APPROACH WAS HARDER TO PERFORM THAN THE 'HAMMOCK', DIFFICULTIES WERE REPORTED WITHDRAWING THE INSERTER WITHOUT DISPLACING THE MINI SLING. ETHICON SELECTIVELY PROVIDED SOME SURGEONS WITH UPDATED INSTRUCTIONS AND SURGICAL TIPS WHILE ETHICON FAILED TO ADEQUATELY UPDATE ITS OWN LABEL, IFU AND MARKETING AND SALES FORCE TO WARN 'ALL' SURGEONS EQUALLY OF TVT-SECUR INCREASED RISKS COMPARED TO OTHER TREATMENT OPTIONS FOR SUI. FINALLY, ETHICON FAILED TO WARN SURGEONS ABOUT PATIENT RISKS FOR MESH EXTRUSION, EROSION, CHRONIC PAIN, WORSENING OF SYMPTOMS, DYSPAREUNIA AND NEED FOR ADDITIONAL SURGERY.

OPINION #5 - DESPITE ETHICON'S KNOWLEDGE OF POST-MARKET DIFFICULTIES FOR THE TVT-S SYSTEM , INCLUDING HIGH FAILURE RATE, BLADDER PERFORATIONS, COMPLAINTS FROM ITS OWN TRAINED KEY OPINION LEADERS (KOL), AND THAT EUROPEAN SURGEONS HAD STOPPED PERFORMING TVT-SECUR IN 2007 BASED ON UNACCEPTABLE RISKS, ETHICON CONTINUED TO MARKET TVT-SECUR IN THE UNITED STATES WITHOUT NOTIFYING SURGEONS OR PATIENTS ABOUT THE INCREASED RISKS. ETHICON DID NOT VOLUNTARILY CONDUCT POST-MARKET SURVEILLANCE STUDIES INCLUDING THE 522 STUDY IN ORDER TO UPDATE ITS AMERICAN LABEL, PHYSICIANS AND WOMEN WITH ACCURATE RISK INFORMATION.

OPINION #6 - BASED ON ETHICON'S MISREPRESENTATIONS TO ITS SALES FORCE AND PHYSICIANS AS WELL AS THE FDA, INCLUDING ITS FAILURE TO CONSIDER AND DISCLOSE THAT THE MOST EXPERIENCED SURGEONS WITH TVT-S EXPERIENCED DIFFICULTIES AND PREMATURE FAILURES WITH THE DEVICE, IMPLANTING SURGEONS WOULD NOT HAVE BEEN ABLE TO PROVIDE PATIENTS WITH AN ADEQUATE INFORMED CONSENT BASED ON KNOWLEDGE OF THE RISKS OF THE TVT-S PRODUCT AS A SIS MINI SLING FOR SUI

OPINION #7 - SURGEONS RELIED ON THE KNOWLEDGE, SKILL AND EXPERIENCE OF ETHICON AS A MAJOR UNITED STATES MEDICAL DEVICE MANUFACTURER TO ADEQUATELY INFORM THEM OF THE RISKS FOR THE TVT-S AND PROVIDE PHYSICIANS WITH SAFE AND EFFECTIVE PRODUCTS TO PERMANENTLY IMPLANT IN WOMEN.

(2) Dr. Parisian is not qualified to offer scientific testimony, and similarly offers no reliable methodology to arrive at her conclusions.

Dr. Parisian does not have sufficient qualifications to present these opinions, nor does she employ a reliable methodology. Although she is a licensed medical doctor and pathologist, she has not treated a patient for nearly 30 years, long before the TVT-Secur was placed on the

market. PM Dep. 57:17-24; 58:4-6. She has never performed surgery to treat pelvic organ prolapse and does not recall if she ever implanted or explanted any medical device; if she had, it was "a long time ago." *Id.* 60:23-61:24.

Dr. Parisian has never participated in any animal or cadaver studies regarding any mesh device, PM Dep. 58:15-20, and has never designed or been involved in any clinical trials, protocols or studies regarding mesh. *Id*. 58:21-59:1; 59:23-60:3. Dr. Parisian has never designed mesh, has never done any biomechanical testing of mesh, and has never done any lab work regarding mesh. *Id*. 59:2-9. She has never tested a polypropylene or mesh explant, nor has she ever inspected or even looked at a mesh explant of any kind under a microscope. *E.g.*, *id*. 59:10-22, 60:4-12.

Dr. Parisian developed her TVT-Secur opinions specifically for litigation and not for any research or study purposes. Exh. E: Parisian 3/8/16 TVT-S Dep. Tr. ("TVT-S Dep. Tr.") 62:23-63:1. She had no involvement with the TVT-Secur or any of its predicate devices during her tenure at the FDA, and she has never spoken with anyone from the FDA regarding her TVT-Secur opinions. *Id*. 66:2-24 (further explaining that during her time at the FDA, she was "involved with some surgical mesh, but nothing specific to urological use. . . . I left before ProtoGen and before TVT.").

Dr. Parisian has never seen a TVT-Secur implanted in the body, has never watched it being implanted, and has never held or even been in the same room as a TVT-Secur device. TVT-S Dep. Tr. 68:20-69:13. She has never done any kind of mechanical testing of the mesh in TVT-Secur and acknowledged she would not "be the right person to counsel" patients about treatment options for stress urinary incontinence. *Id*. 66:25-70:3 (admitting that she does not

have the requisite education, training or experience to implant a TVT-Secur, or counsel a patient about risks and benefits of the device).

When asked whether there are patients who have had no complications with the TVT-Secur, Dr. Parisian responded: "I don't know." TVT-S Dep. Tr. 70:3-9. She had the same answer in regard to whether there are patients who had a good experience with the device: "I don't know. I don't know what the patient experience is." *Id*. 70:6-9. And in response to the question of whether there are women who have had the TVT-Secur safely and effectively implanted, Dr. Parisian acknowledged her lack of understanding: "It's the same answer. I don't know." *Id*. 70:10-15. She also does not know if there are pelvic floor surgeons in the United States who believe the TVT-Secur was safe and effective. *Id*. 70:17-71:71:1; *see also id*. 102:24-105:8 (confirming since prior testimony on the TVT-Secur, she has not conducted any survey or study of pelvic floor surgeons to determine what they understood regarding the product from reading the IFU, from their medical school education, from their surgical training, or from reading medical literature).

Dr. Parisian is not qualified to offer opinions on scientific aspects of urogynecology and material science. This very issue—Dr. Parisian's lack of qualifications on scientific issues—was discussed in *In re Mirena IUD Prods. Liab. Litig.*, -- F. Supp.3d --, 2016 WL 890251, *51-53 (S.D. N.Y. Mar. 8, 2016). There, Dr. Parisian sought to offer opinions on the plaintiffs' theory of "secondary perforation" (i.e., that Mirena could migrate out of the uterus unrelated to insertion) and other scientific issues. *Mirena*, 2016 WL 890251, *52. The district court determined that Dr. Parisian lacked the qualifications to offer this testimony: "Dr. Parisian is a medical doctor, but she has no expertise or special skills related to the uterus or IUDs, nor is she a gynecologist." *Id*. *52; *see also id*. *53 (also finding Dr. Parisian not qualified to opine on a

potential alternative, safer design for Mirena; "Dr. Parisian is not an engineer, nor has she ever designed IUDs, nor does she have any particular expertise in IUDs."). Similarly, the *Mirena* court found Dr. Parisian unqualified to "testify generally about medical standards." *Id*. *56.

Other federal courts have similarly refused to permit Dr. Parisian to opine on scientific issues. In *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp.2d 1323, 1337 (S.D. Fla. 2010), the court explained that "Dr. Parisian is neither a causation expert nor an epidemiologist," and "[w]hile Dr. Parisian's Report contains many opinions on the findings of scientific studies related to Trasylol and the association of Trasylol with various health risks, the Report alone did not allow me to conclude with certainty whether Dr. Parisian's experience at the FDA qualifies her to make such opinions . . . ." Other courts are in accord and have excluded Dr. Parisian's testimony where she sought to exceed the scope of her stated expertise. *See Rheinfrank v. Abbott Labs.*, Case No. 1:13-cv-144-SJD (S.D. Ohio), Order Ruling on *Daubert* Motions (ECF No. 298), at 16-17, attached as Exh. D (excluding Dr. Parisian from testifying about "matters outside the scope of her expertise," including her opinion that certain birth defect risks were "knowable" to Abbott; "she is not qualified to opine that certain risks of Depakote would have been known by 2003 had Abbott conducted research sooner or in a different manner."); *Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *4-5 (E.D. La. Mar. 30, 2000) (in hernia mesh case, excluding Dr.

Parisian where she stated at her deposition that she has never worked with that or any other kind of mesh, is not a surgeon, and has never performed any medical research).[6]

Dr. Parisian is not qualified to offer expert testimony on scientific issues, including causation, product development, risks, design, testing, manufacturing, studies, or the standard of care for treating physicians, and she does not support her vast array of scientific opinions with a sufficient methodology. Any opinions on these issues should be excluded.

B. Dr. Parisian should be precluded from offering testimony about Ethicon's intent, motive, state of mind or bad faith because she is not qualified to offer those opinions; she does not have a reliable basis for her opinions; and these opinions are irrelevant.

Dr. Parisian claims that she will not offer opinions "regarding Ethicon's intent or state of mind." TVT-S Rep. ¶23. Yet again, her report belies that statement. *See, e.g.*, TVT-S Rep. Ops. 1, 2, 4, 5 (recited in Section II(A), above). Dr. Parisian clearly intends to present the jury with her beliefs including matters such as Ethicon's "corporate willingness," and lack of "commitment to conduct[ing] robust … surveillance."

The Court has found testimony on beliefs about the manufacturer's knowledge, state of mind, and whether it acted reasonably to be impermissible. *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *3 (S.D. W. Va. Apr. 28, 2015) ("As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing

---

[6] *See also, e.g.*, *Bartoli v. Novartis Pharms. Corp.*, 2014 WL 1515970, *6 (M.D. Penn. Apr. 17, 2014); *Rowland v. Novartis Pharms. Corp.*, 9 F. Supp.2d 553, 563 (W.D. Pa. 2014); *Mathews v. Novartis Pharms. Corp.*, 2013 WL 5780415, *24-25 (S.D. Ohio Oct. 25, 2013); *Stambolian v. Novartis Pharms. Corp.*, 2013 WL 6345566, *9 (C.D. Cal. Dec. 6, 2013); *Taylor v. Novartis Pharms. Corp.*, 2013 WL 5118945, *7 (S.D. Fla. Apr. 22, 2013); *Hogan v. Novartis Pharms. Corp.*, 2011 WL 1533467, *40 (E.D. N.Y. Apr. 24, 2011); *In Re Heparin Prod. Liab. Litig.*, 2011 WL 1059660, *8 (N.D. Ohio Mar. 21, 2011); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 468 (E.D. N.Y. 2011); *Lopez v. I-Flow Inc.*, 2011 WL 1897548, *11 (D. Ariz. Jan. 26, 2011); *In re Prempro Prods. Liab. Litig.*, 2010 WL 5663003, *2-3 (E.D. Ark. Sept. 16, 2010); *Reece v. Astrazeneca Pharms., L.P.*, 500 F. Supp.2d 736, 745-56 (S.D. Ohio 2007).

an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably."); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013), *on reconsideration in part* (June 14, 2013) ("Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.") (internal citations omitted). Other federal courts have similarly excluded Dr. Parisian on this basis.[7]

C. Dr. Parisian's regulatory opinions are inadmissible because they are irrelevant; amount to legal conclusions; and constitute impermissible "narrative" testimony lacking adequate analysis.

(1) Any opinions premised on misleading or withholding information from the FDA are irrelevant and inadmissible.

Many of Dr. Parisian's opinions are premised on her personal belief that Ethicon withheld information from the FDA or engaged in actions that misled the FDA. *See, e.g.*, TVT-S Rep. Opinions 1-8. These opinions are inadmissible. This information is irrelevant: "whether Ethicon violated particular sections of the FDCA or failed to furnish information to the FDA are not facts in issue in this case under Federal Rule of Evidence 702." *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) ("alleged shortcomings in FDA procedures are not probative to a state law products liability claim"); *see also Fowler v. Boston Scientific*, Case No. 2:13-cv-03932, at 18 (S.D. W. Va. June 3, 2016) (citing *Lewis*).[8] Any

---

[7] *See, e.g.*, Rheinfrank, *supra* at 17 ("Dr. Parisian will also not be permitted to testify as to the 'knowledge, motivations, state of mind, or purposes' of Abbott, its employees, the FDA, or FDA officials."); *In re Mirena*, 2016 WL 890251, *54; *In re Trasylol*, 709 F. Supp.2d at 1338; *Lopez*, 2011 WL 1897548 at *11 (collecting cases).

[8] The FDA is the only entity in a position to determine whether it has been misled. For this reason, the court in *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp.2d 1312, 1329-30 (S.D. Fla. 2010), held that evidence of what information was or was not given to the FDA is only relevant to a fraud on the FDA claim, which is preempted by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350–51 (2001).

opinion that Ethicon submitted false and misleading information to the FDA is preempted; is an irrelevant legal opinion; and is irrelevant to the jury's determination of liability. It should therefore be excluded under Rules 401 as well as 403.

(2) Dr. Parisian's report contains impermissible legal conclusions.

Dr. Parisian's report is likewise inadmissible because her opinions impermissibly constitute legal conclusions. In addition to the numerous statements which impermissibly seek to apply the Food Drug & Cosmetic Act, her approach is evident in the statements concerning alleged duties owed by Ethicon, non-adherence to non-delegable responsibilities, or failure to evaluate foreseeable risks, adequately warn physicians, or comply with current safety and ethical standards. *See, e.g.*, TVT-S Rep. Conclusion, ¶¶318-319.

An expert may not offer "ultimate question" testimony that Ethicon's actions were inadequate: testimony containing legal conclusions impermissibly conveys a witness's unexpressed, and perhaps erroneous, legal standards to the jury. *See, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Heparin*, 2011 WL 1959660 at *8. Thus, Dr. Parisian "may not offer opinion testimony as to the reasonableness of the Defendants' conduct." *Id*. (excluding Dr. Parisian on this basis). *See also, e.g., Pritchett v. I-Flow Corp.*, 2012 WL 1059948, *6 (D. Col. Mar. 28, 2012) (Dr. Parisian's "lengthy written report occasionally lapses into unadulterated legal conclusions which are not only beyond her purview, but which usurp the important functions of the judge and jury").

(3) Dr. Parisian provides an unsupported "narrative" or "regurgitation of facts" to explain her opinions.

Her regulatory opinions also constitute impermissible narrative or, as some courts have deemed her testimony, a "regurgitation of facts." *See, e.g., In re Mirena*, 2016 WL 890251 at

*53. As the district court explained in *In re Fosamax Prods. Liab. Litig*., 645 F. Supp.2d 164 (S.D. N.Y. 2009) when excluding Dr. Parisian, "[a]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on record evidence." *In re Fosamax*, 645 F. Supp.2d at 192. The court also cited *In re Prempro Prods. Liab. Litig*., 554 F.Supp.2d 871, (E.D. Ark. 2008), which overturned a punitive damages award based on Dr. Parisian's testimony in part because she "did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony" and "did not provide analysis, opinion, or expertise." *Id*. at 880, 886. Other courts have similarly found Dr. Parisian's *modus operandi* to provide a "narrative of selected regulatory events and a summary of [internal] documents," where she "merely recites the [FDA's understanding]" without sufficient references to FDA regulations in recitation of the facts.[9]

Dr. Parisian's report here follows the same pattern. Each report contains page after page of references to internal documents, untethered to any explanation of how this vast cache of

---

[9] *See, e.g., Rheinfrank, supra* at 17; *In re Trasylol*, 709 F. Supp.2d at 1338 (finding that Dr. Parisian "does not tie [the regulatory facts] to the opinions that they are intended to support."); *Kaufman v. Pfizer Pharms., Inc.*, 2011 WL 7659333, *10 (S.D. Fla. Aug. 4, 2011) ("[w]hile Dr. Parisian devotes several pages of her report to restating and analyzing FDA regulations, she does not apply any of these regulations . . . to her report."); *see also Lopez*, 2011 WL 1897548 at *10 ("Dr. Parisian's report is a labyrinth that the Court cannot navigate. . . . Dr. Parisian's report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation. . . . This deficiency has also been noted by other courts in excluding such testimony from Dr. Parisian."); *Miller v. Stryker Instr.*, 2012 WL 1718825, *11 (D. Ariz. Mar. 29, 2012) (excluding Dr. Parisian because "much of [her] report regurgitates facts that should be submitted directly to the jury" and where she provided "no analysis or explanation" of her conclusory assertions); *Pritchett*, 2012 WL 1059948 at *7 (D. Col. Mar. 28, 2012) (excluding portions of Dr. Parisian's testimony "regurgitating factual information that is better presented through introduction of documents or non-expert testimony"). Review of state court testimony by Dr. Parisian in a mesh proceeding likewise revealed hours' and hours' worth of narrative testimony by Dr. Parisian, much of which was about the FDA's 510(k) clearance process, issues which this Court has excluded in prior mesh cases. *See* Pl. Resp., Wave I, ECF No. 2148, at Ex. 1 (attaching transcript from *Barba v. Boston Scientific*, C.A. No. N11c-08-050 (Del. Sup. Ct.)).

documents actually supports her opinions. Dr. Parisian's reports otherwise provide a mere bullet-point/paragraph listing of FDA regulations, amounting to handfuls of unexplained and unapplied references to unidentified aspects of federal law. This testimony—as other courts have found—is not reliable nor is it helpful to a jury.

D. Dr. Parisian should not be permitted to opine on foreign regulatory matters because she is not qualified; she does not employ a reliable methodology; and this testimony would not be helpful to the jury.

Dr. Parisian intends to testify on issues including "foreign data," and she refers to foreign regulations in her report. *See e.g.*, TVT-S Rep. ¶¶ 18, 69, 109, 228-230. Dr. Parisian is not qualified to offer expert testimony on foreign regulatory matters: she attests only to a "working familiarity" with "International standards and requirements"—hardly a basis to deem Dr. Parisian qualified as an expert to present this material to a jury. *E.g.*, TVT-S Rep. ¶18. As the district court found in *In re Mirena*, "Dr. Parisian will not be allowed to opine on foreign regulatory issues. Dr. Parisian is admittedly not an expert in the laws of foreign jurisdictions, and therefore is not qualified to testify on those subjects." *In re Mirena,* 2016 WL890251 at *53. In addition, as here, "[t]here is no reason to believe that the regulatory framework of [other countries] is similar to the FDA's system." *Id*. (also finding that Dr. Parisian's report and proposed testimony in this area "is a recitation and reports and regulatory actions, with little or no analysis, which is not proper expert testimony" and ruling that "she may neither summarize foreign regulatory history nor imply that an action required abroad was necessarily required in the U.S."). Any opinions by Dr. Parisian on foreign regulatory issues should thus be excluded.

E. Dr. Parisian's testimony about the TVT-Secur's warnings should be excluded because she is not qualified and fails to use a reliable methodology.

Dr. Parisian opines that the TVT-Secur warnings were inadequate, claiming that the labeling "failed to warn physicians of the difficulties of the insertion for SUI, the difficulties

experienced with the insertion tools and the significant learning curve seen in physicians already familiar with this type of surgery." TVT-S Rep. ¶319. She contends the labeling had inadequate directions for use and "inadequate warnings and lack of adequate information about potentially serious, permanent and life-altering risks for the product when implanted for SUI." *Id.*

As set forth below, Dr. Parisian's warnings opinions are not based on sufficient qualifications or a reliable methodology.[10]

(1) Dr. Parisian is not qualified to opine on the TVT-S warnings.

Whereas some courts have found Dr. Parisian to be sufficiently qualified to opine on product warnings, *see, e.g.*, *In re Mirena*, 2016 WL 890251 at *55, Dr. Parisian's testimony reveals that in this case, she is not adequately qualified to offer opinion testimony. *See, e.g.*, *Rowland*, 9 F. Supp. 2d at 562 (excluding Dr. Parisian as unqualified to testify what prescribing oncology physicians would have done with different warnings because it would require an impermissible degree of speculation from Dr. Parisian, who is not an oncologist); *Reece*, 500 F. Supp. 2d at 745-46 (S.D. Ohio 2007) (excluding Dr. Parisian from offering testimony on, e.g., whether defendants provided physicians with adequate warnings: "plaintiff has not demonstrated that there is anything in Dr. Parisian's background or training that qualifies her to testify as an expert on chronic pain patients, rhabdomyolysis, or renal failure;" also finding that she did not use a scientifically valid methodology where she did not perform any testing or research).

[10] Dr. Parisian's testimony on the TVT-Secur is contained both in the March 8, 2016, deposition testimony in MDL 2327, as well as testimony on February 12, 2015 (also for the TVT-Secur) in *Garcia v. Walss et al.*, 103rd Judicial District, Cameron County, Texas (No. 2013-DCL-3511-D). *See* Exh. E: Parisian 3/8/16 TVT-S Dep. Tr. ("TVT-S Dep. Tr.") 7:18-8:6 (parties' agreement that the deposition in *Garcia* may be used as in the MDL); Exh. F: Parisian 2/12/15 (Garcia) TVT-S Dep. Tr. ("Garcia Dep. Tr.").

In addition to the details set forth above (e.g., lack of any experience with or testing of mesh, lack of understanding of any patient experience), the following additional facts point to Dr. Parisian's lack of qualifications as directly bearing on warnings. Dr. Parisian has never practiced medicine in the fields of surgery, gynecology, urology, or urogynecology. Garcia Dep. Tr. 94:12-95:8. She has no experience treating women for SUI with surgical mesh. *Id*. 94:12-13; 99:2-6. She has never seen how a TVT-Secur is implanted, has never implanted one herself, and admits that she lacks the expertise to do so. *Id*. 99:18-23; 114:2-10.

Dr. Parisian has never designed pelvic mesh or any other product from the treatment of SUI. Garcia Dep. Tr. 101:20-24. She has never designed a clinical trial for surgical mesh or for any SUI product. *Id*. 101:9-14. She has never conducted any clinical research regarding surgical mesh or SUI. *Id*. 101:15-19. Dr. Parisian has never conducted any biomechanical testing for pelvic mesh in general and has never tested the TVT-Secur device. *Id*. 102:1-4. She has never conducted any biocompatibility studies for the mesh and has not conducted any clinical trial or clinical research regarding polypropylene. *Id*. 116:21-23. She has never performed a Device Design Safety Analysis or a Failure Mode Evaluation Analysis. *Id*. 103:15-104:4. Dr. Parisian admits she is not an expert in the design process for pelvic mesh. *Id*. 104:18-105:7.

Dr. Parisian likewise acknowledged her lack of pertinent experience while at the FDA and her lack of education, training and experience regarding implantation or counseling of patients for the TVT-Secur. TVT-S Dep. Tr. 66:14-24, 67:5-20, 68:23-69:13, 69:18-70:2, 67:21-68:22, 102:24-105:8. She does not have any information about the patient experience, such as whether patients have had no complications—or experiences with the product being safe and effective. *Id*. 70:3-9. Nor does Dr. Parisian know if pelvic floor surgeons believe the TVT-S is safe and effective. *Id*. 70:10-71:1.

Dr. Parisian seeks to opine on the warnings, but she has never drafted an IFU or patient brochure. TVT-S Dep. Tr. 71:2-5. She does not know the risks that were associated with the TVT-S. *Id.* 93:10-101:5. She has not identified what words needed to be added or removed from the TVT-S IFU to make it adequate. *Id.* 71:6-13.

Dr. Parisian has never spoken with a doctor who has implanted a TVT-S; she has never spoken to a pelvic floor surgeon about the TVT-S; and she has read only one deposition of an implanting physician (in *Garcia*). *Id.* 71:14-72:1; 84:4-18. She did not review any professional education materials regarding TVT-S. *Id.* 72:16-20, 75:17-78:8. She has not conducted any survey or study of pelvic floor surgeons about the risks they would understand from reading the patient brochure. *Id.* 84:16-85:3. In fact, she has not conducted any survey or study of pelvic floor surgeons to determine whether they ever read the IFU—or to determine what risks they understood from the IFU, or from their education, surgical training, or review of relevant medical literature. *Id.* 104:4-105:12. She has no opinion whether pelvic floor surgeons implanting the TVT-Secur should read the medical literature, testifying: "Yeah, I don't have an opinion about that. I mean, they're responsible for their practice." *Id.* 105:9-12.

Despite her dearth of experience, despite having performed no tests, clinical trials, or research on the design of surgical mesh generally or TVT-Secur, despite never having spoken to any physician about the IFU or patient brochure, and despite not knowing the risks at the pertinent timeframe, Dr. Parisian nevertheless seeks to opine on the warnings provided to pelvic surgeons for the TVT-S. Nothing about Dr. Parisian's knowledge, skill, experience, training, or education qualifies her to offer these opinions. She should be precluded from offering any opinion on these subjects based on her lack of sufficient qualifications alone.

(2) Dr. Parisian does not apply a reliable methodology.

Dr. Parisian's warnings opinions also fail because she has not employed a reliable methodology.

Under the FDA regulations and under the common law, there is no duty to warn of risks commonly known to device users. *See* 21 C.F.R. §801.109(c); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (manufacturer had duty to warn of risks that "were not well known to the medical community"); *see generally* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j (1998) (stating there is no duty to warn of "obvious and generally known risks"). Yet Dr. Parisian has not applied any reliable methodology to determine what physicians already know and what risks should have been disclosed based on the medical evidence.

Dr. Parisian did not review the TVT-Secur published medical literature to compare the risks disclosed in that literature versus the risks in the IFU of patient brochure. TVT-S Dep. Tr. 78:1-6; *see also id*. 93:9-95:4 (admitting she does not know when risks such as chronic dyspareunia with SUI or chronic pain was first discussed in published medical literature and stating that she "did not do a search" . . . "to look for when they knew certain things"). She further admits that the FDA never found the material in the IFU to be deficient and never proposed label changes for the TVT-Secur. Garcia Dep. Tr. 232:8-233:23. Dr. Parisian did not conduct a readability study of the TVT-Secur IFU, id. 124:5-124:13, and did not conduct a survey of surgeons to determine what information the surgeons gleaned from the IFU. *Id.* 121:8-121:22. She has never spoken with a medical doctor about her criticisms of the IFU. *Id.* 33:16-33:18. She has never conducted any survey or studies of patients as to their understanding of the TVT-Secur patient brochure, nor did she ask any pelvic floor surgeon about the brochure. TVT-S Dep. Tr. 83:14-85:4.

In sum, regarding warnings, Dr. Parisian is unqualified and her lack of any methodology or research to support her conclusions renders her testimony unreliable. Instead, she offers opinions based on personal belief and mere speculation. This lack of qualifications and reliable methodology is indelibly tied to Dr. Parisian's ability to offer an expert opinion to the jury about whether the product IFU and patient brochures were adequate to warn surgeons of the known risks of the product.

As district courts recognize, to opine about the sufficiency of a warning, the expert must "have a sufficient basis for understanding what information is needed by a doctor in making his or her prescribing decision. Without knowing the baseline of what information is needed, it is not possible to opine meaningfully on the information's adequacy for that purpose." *Calisi v. Abbott Labs*, 2013 U.S. Dist. LEXIS 139257, *26 (D. Mass. Sept. 27, 2013) (excluding regulatory expert's opinion about sufficiency of warnings for a physician); *see also In re Welding Fume Prods.*, 2005 WL 1868046, at *7 (N.D. Ohio Aug. 8, 2005) (excluding expert's opinion regarding warning because the incorrect standard applied by the expert "does not necessarily translate to a legal warning requirement, nor does it necessarily imply liability"); *Am. Med. Sys. v. Laser Peripherals, LLC*, 712 F. Supp. 2d 885, 900-901 (D. Minn. 2010) (excluding expert's testimony where she did not apply standard correctly).

Here, Dr. Parisian provides no basis for her opinion of what Ethicon "should have done" and is likely the result of Dr. Parisian's lack of expertise in warnings and labels for medical devices. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611 (granting motion to exclude plaintiff's warnings expert who had never developed a warning or a label, who had no familiarity with federal regulations regarding IFUs and who had no familiarity with whether FDA or other manufacturers' IFUs include supporting data; the expert was "unqualified to testify on the

specific issue of product warnings, as evidenced by his lack of familiarity with the process. To the extent that Dr. Shull seeks to opine that surgeons did not receive adequate warnings from Bard, he is similarly unqualified to do so."). Dr. Parisian's warnings opinions should be excluded.

F. Dr. Parisian should not be permitted to testify about any product other than TVT-Secur (*see* Exhibit A).

Finally, Dr. Parisian has been designated as an expert in three cases which involve TVT-Secur, the product for which she prepared an expert report. *See* Exh. A. She was also designated as an expert in an additional five cases involving other mesh products, but did not provide an expert report for those cases. The parties entered into a Stipulation, filed in each of those respective cases, whereby those Plaintiffs withdrew their expert designation for Dr. Parisian. Accordingly, Dr. Parisian should not be permitted to testify in those matters.

CONCLUSION

Ethicon's motion to exclude any opinions by Suzanne Parisian, M.D., regarding the TVT-Secur should be granted. Ethicon prays for all other relief to which it is entitled.

Respectfully submitted,

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)

P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones